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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html.

DATES: The meeting will be held on Wednesday, March 12, 2014 from 8:30 a.m. until 5:00 p.m. and Thursday, March 13, 2014 from 8:30 a.m. until 4:30 p.m.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Hubert H. Humphrey Building, Room 800, Washington, D.C. 20201.

FOR FUTHER INFORMATION CONTACT: Ivor Pritchard, Ph.D., Director (Acting), Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101

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SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., Wednesday March 12. Following opening remarks from Dr. Jerry Menikoff, OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, the Subcommittee on Harmonization (SOH) will give their report, presenting recommendations on cluster randomized trials and informed consent.

SOH was established by SACHRP at its July 2009 meeting and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The afternoon presentation will focus on a discussion of cluster randomization, risk assessment, and consent requirements.

Following opening remarks on the morning of March 13, the Subpart A Subcommittee (SAS) will give their report, focusing on recommendations for a remodeled concept of engagement in human subjects research. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A

of 45 CFR part 46 in the current research environment; this subcommittee was established by SACHRP in October 2006.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACHRP at the address/phone listed above at least one week prior to the meeting. Members of the public will have the opportunity to provide comment during the public comment periods; pre-registration is required for participation in the public comment session. Individuals who are on-site may pre-register the day of the meeting; individuals participating through webcast should pre-register by contacting the Executive Director, SACHRP, by COB March 6. Individuals who would like to submit written statements should email or fax their comments to SACHRP at least five business days prior to the meeting.

Dated: February 18, 2014.

Ivor Pritchard,

Director (Acting), Office for Human Research Protections,

Executive Secretary, Secretary's Advisory Committee on

Human Research Protections.

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